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In re Application of
Megede JZ et al.
Serial No. : 09/899,575
Filed : 5 July 2001
Attorney Dkt No. :PP01631.102 2302-1631.21

Decision on Petition

This is in response to the petition under 37 CFR 1.144 filed 1 September 2005, to request review of a restriction requirement.

## BACKGROUND

A review of the file history shows that the application was filed on 5 July 2001 under 35 USC 111(a) as a CIP of 09/610,313 with 96 claims drawn to expression cassette comprising various polynucleotide sequences.

Examiner mailed a restriction requirement on January 5, 2005, in which the 96 claims were divided in to 20 groups under 35 U.S.C. 121, Because the restriction requirement among Groups I-XX is not under review, the groups I and III-XX are not listed herein. The petition concerns the division within elected Group II:

II. Claims 2-6 and 38-46, drawn to an expression cassette comprising a polynucleotide of SEQ ID NOs: 46, 119-127, and 131-133, classifiable in class 435, subclass 320.1.

Within elected Group II, the examiner required applicants to elect from SEQ ID NOs: 46, 119-127, 131, 132, and 133. The sequences encode HIV Env polypeptides.

Examiner also indicated that there are no claims encompassing a generic HIV polypeptide, which indicates that the SEQ ID NOs are independent and there is no disclosure of relationship (percent sequence identity) in the specification between the claimed sequences in each group.

In response, on March 7, 2005, Applicants elected Group II and SEQ ID NO:120 with traverse.

In the Office action mailed June 2, 2005, the examiner indicated that the arguments for the traversal were not persuasive and made the restriction FINAL.

In a response filed on August 31, 2005, Applicants again requested consideration of the restriction arguing that structure of the polypeptide encoded by the claimed polynucleotide is not relevant, even if the structure was relevant, Examiner has provided no evidence that the polynucleotides encode polypeptides with different structure, Examiner provided no evidence that the searching of all sequences would be burdensome and that applicant provided clear evidence that a high degree of homology between the claimed sequences, establishing that searching all sequences together would not be unduly burdensome and finally filing of separate applications would present financial burden.

On September 6, 2005, Applicants petitioned to review the restriction requirement between the inventions of Group II. The petition is timely filed under 37 CFR 1.144.

## DISCUSSION

The application, file history and petition have been considered carefully. The sequence alignments and sequence comparison table filed by the applicants has also been considered fully.

Applicants request reconsideration and withdrawal of the Restriction between the sequences of Group II, all of which, according to applicants encode HIV envelope glycoproteins. Applicants argue that indeed, by restricting to a single sequence, the Office has prevented them from claiming the full scope of their invention. Applicants recite from M.P.E.P. § 803.02.

> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Applicants argue that all Group II sequences share a common utility (encoding an immunogenic HIV Env polypeptide) and possess a substantial structural feature (particular polynucleotide coding sequences) essential to that utility and that the claimed polynucleotides do not differ in structure or function but differ only in sequence and that the assertion that the sequences are structurally different (along with the irrelevant assertion that they encode structurally different polypeptides) is in error and cannot support the Restriction. Therefore, Restriction among the different Env-encoding sequences should be withdrawn.

The argument concerning the common utility is not persuasive because it is not commensurate with the claims. The claims of group II are simply drawn to an expression cassette comprising a sequence having 90% sequence identity to a group of polynucleotides. None of the claims in group II requires a polynucleotide that encodes an immunogenic HIV envelope polypeptide as alleged by the applicants.

Furthermore, applicants' argument that all Group II sequences possess substantial structural feature essential to a common utility and that the polynucleotides do not differ in structure but only differ in sequence is not persuasive. This is because, as evidenced by the sequence comparison provided by applicants, the sequences in claim 38 differ from each other by as much as 15% in their sequence identity. For example SEQ ID NO:131, 132, 133 are only 85%, 89%, 88% identical to SEQ ID NO:122 respectively. A difference of 15% is a significant difference and cannot be concluded as minor difference. Next, applicants argument that the polynucleotides share a common utility and possess substantial structural feature "essential to that utility" is also not persuasive for several following reasons.

First, the claims are not directed to polynucleotides which are required to encode an "Env" polypeptide as alleged, but to polynucleotides that are 90% identical to the claimed polynucleotide sequences. Polynucleotides which can vary by as much as 90% from SEQ ID No 120 are not limited to those which encode the "Env" polypeptide but include polynucleotides which would have frameshift or truncations such that no polypeptide was encoded or such that an unrelated polypeptide may be encoded from a different open reading frame.

Second, even if claims were directed to polynucleotides encoding "Env" polypeptides, applicants have not identified and provided the Examiner, the "substantial structural feature essential for that utility" i.e., envelope protein utility, such that polynucleotides having such structures can be easily identified. A perusal of the specification does not provide any information regarding any structural feature that can be used to identify "Env" encoding polynucleotides. A search in the non-patent literature indicates that there are several types of "Env" polypeptides such as gp41, gp120, gp140, gp160 etc. with each polypeptide having specific structural and functional and immunogenic properties. It is also evident from the literature that these proteins are highly specific such that they are all not obvious variants of each other. Furthermore, for the sake of argument if it is considered that the encoded polypeptides have the same utility, i.e., serve as envelope polypeptide of HIV, each encoded polypeptide will have

different structure because of different amino acid sequence and a different function even as an envelope protein.

Applicants' next argument that, the polynucleotides in question do not differ in structure but only differ in sequence is misplaced. This is because, the structure of a polynucleotide is dependent on its sequence or the structure *is* defined by the sequence. Therefore, if two polynucleotides have different sequences they have different structure and different sequences are considered as different inventions. Consequently, searching different polynucleotides does cause undue search burden on the Examiner/Office. Furthermore, the search of these polynucleotides is not limited to the sequence database of the issued patents database maintained at the Office but involves the search of several public and commercial databases.

Applicants also argue that if the current restriction groupings are maintained, they will have to file 58 separate applications and the related expenses would be an undue burden on them. Applicants also argue that 58 additional applications would constitute even more burden on the Office, particularly in light of the current examination backlog. Such arguments also are not found to be persuasive. All applicants have to bear the burden of patenting their inventions, whether the invention involve one or 58 different sequences. The Office is under no obligation to examine more than one invention in order to reduce the expenses for the applicant. It is noted that the burden to the Office is not lessened by examining all the sequences that applicants have requested as opposed to the burden of examining 58 different applications.

Finally, applicants recite the O.G. notice of November 19, 1996, (MPEP 2434 at 1192 O.G. 68 (Nov. 19, 1996)) that the PTO believes that allowing applicants to claim up to ten (10) independent and distinct nucleotide sequences in a single application will promote efficient, cost effective examination of these types of applications. While the above O.G.Notice is acknowledged, it should be noted that the sequence waiver is permissive in nature and not mandatory and the instant sequences, as claimed, are not limited to simple polynucleotide sequences, but encompass variants. As such, and absent an allowable generic linking claim, restriction to the genus of expression cassettes comprising a polynucleotide having 90% identity to SEQ ID No 120 is appropriate.

## DECISION

For these reasons, the petition to withdraw the restriction requirement between the sequences of Group II is **DENIED**.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner to consider the RCE and response filed on 26 July 2005 and to prepare an action which is consistent with this petition decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 571-273-8300.

Jasemine Chambers
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